

510(k) Summary of Safety and Effectiveness

(APPENDIX II)

1. Submitted by: Convergent Imaging Solutions
49 First Avenue, Suite B
Ottawa, Ontario K1S 2G1, Canada SEP 26 2008

2. Date of Preparation: July 02, 2008

3. Name, Title and Phone Number of Contact

Mathew A. Thomas
Phone: 613-239-0421 Fax: 801-315-9085

4. Tradename and Common Name of the Device

Tradename:	UniSyn
Common Name:	Image Processing (Image Fusion) Software

5. Intended Use

UniSyn is a software application for image registration and fusion display of scanned image data from CT, PET, SPECT and MR scanners. It is to be used by qualified radiology and nuclear medicine professionals. UniSyn creates multi-planar reformat and maximum intensity projection displays of the data and provides measurements such as area, volume and Standard Uptake Values for user defined regions on the image.

6. Device Description

UniSyn is a **software only** package designed for use on Intel Pentium and higher compatible computers running Microsoft Windows XP and later operating systems. It loads and writes images using a proprietary format.

UniSyn provides the following features:

- manual registration of images, where users can use user interface widgets to align the images in three dimensions;
- automated registration of images from hybrid PET-CT and SPECT-CT scanners, which provide the registration parameters in their image headers;
- multi-planar reformat (MPR) and image triangulation using cursors: linked transverse, sagittal and coronal views. When the user moves a cursor on one view, the corresponding orthogonal planes of the image are computed and displayed on the other.
- image fusion with variable opacity
- Maximum Intensity Projection (MIP)
- 3D Render

- Surface Render
- 2D regions of interest and 2D statistics such as area
- 3D volumes of interest and 3D statistics such as volume, average Standard Uptake Value (SUV) and maximum SUV
- user configurable layouts: type of image (ie which modality and what type of display: one of MIP, MPR/), size, color map, position – can be preconfigured;
- triangulation from MIP image: if the user clicks on the MIP image when it is in the coronal view, the MPR/fusion displays will update their position to that point
- color maps individually assigned for fusion and non-fusion views
- screen capture to clipboard and to disk

7. **Predicate Device:** Common Name: Syntegra Image Fusion
Manufacturer: Philips Medical Systems
510K#: K041182

Common Name: Medical Image Merge (Image Fusion)
Manufacturer: Syntermed (now MIMVista)
510K#: K001276

8. Technological Comparison to Predicate Devices:

Feature	Syntegra	Medical Image Merge	UniSyn	Comments
software device	✓	✓	✓	
intended use				Similar.
multimodality registration	✓	✓	✓	Identical feature.
multimodality fusion display	✓	✓	✓	Identical feature.
fusion opacity control	✓	✓	✓	Identical feature.
Regions of Interest	✓		✓	Identical feature.
Standard Uptake Value Calculation	✓		✓	Identical feature.
Multiplanar reformat with triangulation	✓	✓	✓	Identical feature.
Maximum Intensity Projection	✓	✓	✓	Identical feature.
3D (Surface) Render	✓		✓	Identical feature.
Variable color maps	✓	✓	✓	Identical feature.
configurable image presentation layouts	✓		✓	Identical feature.
PC hardware	✓	✓	✓	Identical feature.
automated registration using patient outlines and fiducial markers	✓			
export of 3D contours for treatment planning	✓			

Conclusion:

UniSyn is substantially equivalent to the predicate devices Syntegra and Medical Image Merge, in terms of its image processing and display capability. UniSyn does not introduce any new features or issues of safety and effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 26 2008

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Mathew A. Thomas
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OTTAWA ONTARIO K1S 2G1
CANADA

Re: K081987

Trade/Device Name: UniSyn

Regulation Number: 21 CFR 892.2050

Regulation Name: Picture Archiving and Communication System

Regulatory Class: II

Product Code: LLZ

Dated: August 25, 2008

Received: September 2, 2008

Dear Mr. Thomas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement (APPENDIX VII)

510K Number (if known): K081987

DEVICE NAME: UniSyn

SUBMITTER NAME: CONVERGENT IMAGING SOLUTIONS

INDICATIONS FOR USE:

UniSyn is a software application for image registration and fusion display of scanned image data from CT, PET, SPECT and MR scanners. It is to be used by qualified radiology and nuclear medicine professionals. UniSyn creates multi-planar reformat and maximum intensity projection displays of the data and provides measurements such as area, volume and Standard Uptake Values for user defined regions on the image.

(Please do not write below this line. Continue on another page if needed.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)



(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number K081987